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November 17, 2011

Laura A. Brust
Assistant General Counsel
American Chemistry Council
700 Second Street NE
Washington, DC 20002

Re: FOI Case No. 39419

Dear Ms. Brust:

This acknowledges your November 7, 2011, Freedom of Information Act (FOIA) request addressed to the FOI Officer at the National Institutes of Health. Your request has been forwarded to our office due to our responsibilities under FOIA. You requested a copy of all records related to the publication "Occupational Exposure to Formaldehyde, Hematotoxicity and Leukemia-Specific Chromosome Changes in Cultured Myeloid Progenitor Cells" authored by Zhang et al. (2010) (the "Study") and published in the Journal of Cancer, Epidemiology, Biomarkers & Prevention. The Records requested may be a part of, or otherwise associated with, Grants R01ES017452 (not R01ES01752 per your request) awarded to Luoping Zhang and P42ES004705 awarded to Martyn T. Smith by the National Institute of Environmental Health Sciences of the National Institutes of Health (NIH) (not under the Intramural Research Program of the National Cancer Institute per your request). The Records requested include the following except for the Records in Attachment A to your letter (which the National Cancer Institute already has provided in response to a previous FOIA request):

1. All Records related to the protocol and methodology for conducting the Study. These include all Records concerning:
 - a. Exclusion criteria for Study subjects.
 - b. The frequency-matching methodology that has been applied in the Study.
 - c. Statistical methods applied for evaluation of the data collected, to include assumptions related to the distribution of the aneuploid cells among individuals in the unexposed and exposed Study subjects (i.e., normal or clonal).
 - d. Methods used for conducting the Fluorescence *In situ* Hybridization (FISH) analysis, including the cutoff values for monosomy 7 and trisomy 8, and irrespective of whether or not intact metaphases were required for analysis.
2. All Records related to the information and data obtained regarding the Study subjects. These include all Records (whether in English or Chinese) concerning:

Page 2 - Laura A. Brust

- a. Original questionnaires administered to Study subjects by trained interviewers requesting such information as occupational history, environmental exposures, medical history and current medications, and past and current tobacco and alcohol use.
 - b. Spreadsheets or other Records that were developed in order to summarize and/or analyze the information collected as part of the questionnaires administered to each Study subject.
 - c. Records identifying the specific factory at which each Study subject was employed.
 - d. Records identifying the specific Chinese or Western medicines used by each Study subject.
 - e. Records containing the laboratory analytical results from the exposure monitoring conducted with UME diffusion samplers worn by each Study subject.
 - f. Data and methods used for estimating 8-hr time weighted average levels for control subjects and exposed subjects.
 - g. Records that provide the Study subjects' individual clinical chemistry results, to include laboratory standardization, laboratory reference values and interlaboratory comparison statistics.
3. All Records related to any analysis, results (including but not limited to photomicrographs), findings and conclusions resulting from use of the protocol and methodology Records requested in (1) above, with respect to the information and data in the Records requested in (2) above, that have been conducted and that are not included in the published summary of the Study. These include all Records concerning:
- a. All FISH analyses of aneuploidy measured *in vitro* in progenitor cells of exposed and non-exposed workers, to include incidence of trisomy of chromosome 7 or monosomy of chromosome 8.
 - b. All FISH analyses of aneuploidy measured by formaldehyde *in vitro* in progenitor cells.

We will send you all material consistent with the exemptions recognized by the FOIA. It is Department of Health and Human Services (DHHS) policy to expunge social security numbers, EIN numbers, birth dates, percentage of effort, institutional base salary, source of private support, pending support, and any patentable material wherever they appear throughout the grant material. If you feel that this information should not be excluded from the material, please advise me and I will consult with the NIH Freedom of Information Officer.

We are asking the grantees to advise this office if release of the material you requested will adversely affect any patent rights or reveal other confidential commercial or financial information. Subsequent to receipt of such advice this office will make a decision regarding releasability. We will do everything possible to comply with your request in a timely manner.

Page 3 - Laura A. Brust

Provisions of the FOIA allow us to recover part of the cost of complying with your request. We shall charge you for records in accordance with the DHHS FOIA regulations as they apply to commercial-use requesters; i.e., you will be charged for duplication at 10-cents per page; and for search and review time at the hourly rate (\$23.00, \$46.00, \$83.00) of the searcher and reviewer. Please be advised that the DHHS FOIA Regulations allow us to charge for search time even if we do not locate any responsive records or if we determine that some or all of the responsive records are exempt under one of the FOIA's nine exemptions. If there are any fees associated with processing this request, you will be sent an invoice with our final response. Your \$500 fee limit has been noted. We will contact you if fees are expected to exceed that amount.

Please feel free to contact me at the phone number or e-mail address shown above for additional information or to inquire about the status of your request.

Sincerely,

A handwritten signature in cursive script that reads "Kim Minneman".

Kim L. Minneman
Freedom of Information Coordinator